DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2015

Zimmer Spine, Incorporated
Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K143297
Trade/Device Name: InFix® Anterior Lumbar System, Ardis® Interbody System, BAK® Interbody Fusion System, BAK/C® Anterior Cervical Interbody Fusion System, TraXis® Vertebral Body Replacement (Ti and VUE)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: November 14, 2014
Received: November 17, 2014

Dear Ms. Semlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143297

Device Name
InFix® Anterior Lumbar System

Indications for Use *(Describe)*
When used as a vertebral body replacement device, the InFix System is intended for use in the thoracic and/or lumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The InFix System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The InFix implant is intended to be used with bone graft.

When used as an intervertebral body fusion device, the InFix System is indicated for use with autogenous bone graft at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the InFix implant is intended to be used with supplemental fixation.

For both of the indications listed above, the InFix implant is intended to be implanted via an open anterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143297

Device Name
Ardis® Interbody System

Indications for Use *(Describe)*
The Ardis Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non- operative treatment.

The Ardis Interbody System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143297

Device Name
BAK /C® Anterior Cervical Interbody Fusion System

Indications for Use *(Describe)*
The BAK/C implant is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. BAK/C implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143297

Device Name
BAK® Interbody Fusion System

Indications for Use *(Describe)*
The BAK device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels form L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels(s). BAK devices are to be implanted via an open anterior or posterior approach. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Standard BAK devices and BAK/Proximity devices are to be implanted via an open anterior or posterior approach. BP/Lordotic devices are to be implanted via an open anterior approach.

All BAK devices are also indicated for laparoscopic implantation at the L4-L5 and L5-S1 levels for the same clinical indications described above.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143297

Device Name
TraXis® Vertebral Body Replacement (Ti and VUE)

Indications for Use *(Describe)*
Cadence and TraXis are vertebral body replacement devices that are intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with bone graft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

	510(k) SUMMARY ***Interbody Fusion and Vertebral Body Replacement (VBR) Devices***

Date of Summary Preparation: February 11, 2015

Submitter:

Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439
USA

Establishment Registration Number: 2184052 (Minneapolis)

Company Contact (Primary):

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Common Name(s):
Interbody Fusion Systems
Vertebral Body Replacement Systems

Device/Trade Names(s):
Ardis® Interbody System
BAK® Interbody Fusion System
BAK/C® Anterior Cervical Interbody Fusion System
InFix® Anterior Lumbar System
TraXis® Vertebral Body Replacement (TraXis Ti, TraXis VUE)

Device Classification: Class II

Regulation Number and Product Code(s):
21 CFR § 888.3080 / MAX
Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR § 888.3060 / MQP
Spinal Vertebral Body Replacement Device

Primary Predicate Device

The primary predicate device for this submission is the currently marketed *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* listed below. The purpose of this submission is to update product specific package inserts (IFU) with MRI Conditional language only.

Product Name	FDA 501(k) or PMA Numbers	Classification	Primary Code
InFix Anterior Lumbar System	K132790	Class II	MAX 21 CFR § 888.3080 MQP 21 CFR § 888.3060

Additional Predicate Devices:

Product Name	FDA 501(k) or PMA Numbers	Classification	Primary Code
Ardis Interbody	K133184	Class II	MAX 21 CFR § 888.3080
BAK Interbody	P950002	Class II *Re-classified 2007*	MAX 21 CFR § 888.3080
BAK Proximity	P950002	Class II *Re-classified 2007*	MAX 21 CFR § 888.3080
BAK / C Interbody	P980048	Class II *Re-classified 2007*	MAX 21 CFR § 888.3080
InFix	K031672	Class II	MQP 21 CFR § 888.3060
TraXis Ti	K033517	Class II	MQP 21 CFR § 888.3060
TraXis VUE	K033517	Class II	MQP 21 CFR § 888.3060
Zimmer TMT VBR-L	K070754	Class II	MQP 21 CFR § 888.3060
Zimmer TMT TM Ardis	K113561	Class II	MAX 21 CFR § 888.3080
Zimmer TMT Vista-S	K133784, K111983	Class II	ODP 21 CFR § 888.3060
Zimmer TMT TM-400*	K120203	Class II	MAX 21 CFR § 888.3080 MQP 21 CFR § 888.3060

**FDA clearance for MRI Labeling*

General Device Description:

The *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* are intended for use in the cervical, thoracic and/or lumbar spine to mitigate and/or replace the disc space. The interbody fusion devices are intended for use with autogenous bone graft in patient with degenerative disc disease (DDD); defined as discogenic back pain and degeneration of the disc space. The vertebral body replacement (VBR) devices are intended to replace a collapsed, damaged or unstable vertebral body. VBR devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column in the absence of fusion for a prolonged period.

The subject devices are to be implanted by either an anterior approach or a posterior approach or a transforaminal approach per the indications for use and/or the instructions of the surgical technique guide(s). The BAK devices are also indicated for laparoscopic implantation, per the device indications for use.

The *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device System* implants are manufactured from medical grade Ti-6Al-4V ELI titanium alloy or Polyether ether ketone (PEEK) OPTIMA with tantalum markers. The InFix system allows for the use of an optional Endcap made from Ultra High Molecular Weight Polyethylene (UHMWPE).
System(s) with instrumentation, the instruments are manufactured from one (or more) of the following materials: Surgical Grade Stainless Steel, Aluminum, Silicone Rubber, Radel, AITiN PVD coating, TiN PVD Coating, Nylon.

The subject implants are provided terminally sterilized with the exception of the InFix System, which is provided Non-Sterile. The InFix System must be sterilized by the end-user/healthcare facility prior to use. The subject implants are designed for single-use only. The System(s) instrumentation is provided to the end-user/healthcare facility clean but not sterile. The end-user/healthcare facility ensures through cleaning and sterilization of instrumentation before use.

Indications for Use:

Product Name	Indications For Use
Ardis Interbody System	The *Ardis* Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non- operative treatment. The *Ardis* Interbody System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.
BAK Interbody Fusion System	The BAK device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels form L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels(s). BAK devices are to be implanted via an open anterior or posterior approach. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Product Name	Indications For Use
	Standard *BAK* devices and *BAK/Proximity* devices are to be implanted via an open anterior or posterior approach. *BP/Lordotic* devices are to be implanted via an open anterior approach. All BAK devices are also indicated for laparoscopic implantation at the L4-L5 and L5-S1 levels for the same clinical indications described above.
BAK / C Anterior Cervical Interbody Fusion System	The BAK/C implant is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. BAK/C implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone.
InFix Anterior Lumbar System	When used as a vertebral body replacement device, the *InFix* System is intended for use in the thoracic and/or lumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The *InFix* System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The *InFix* implant is intended to be used with bone graft. When used as an intervertebral body fusion device, the *InFix* System is indicated for use with autogenous bone graft at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the *InFix* implant is intended to be used with supplemental fixation. For both of the indications listed above, the *InFix* implant is intended to be implanted via an open anterior approach.
TraXis Vertebral Body Replacement	Cadence and TraXis are vertebral body replacement devices that are intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). These devices are designed to restore the biomechanical integrity of the anterior, meddle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with bone graft.

Summary of Technological Characteristics:

The technological characteristics remain the same between the subject *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* as the predicate devices listed above. There are no changes to the implants (interbody and VBR) and instrumentation within this submission. This submission is only proposing labeling updates regarding interactions with magnetic fields during Magnetic Resonance Imaging (MRI) with respect to patient safety.

All the technology characteristics remain the same: same system's intended use, same mechanical and functional scientific technology; same materials and the same substantially equivalent performance characteristics.

Summary of Performance Testing:

Magnetic Resonance Imaging (MRI) testing of interbody fusion and VBR devices contained in the *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* were assessed and tested appropriately to design controls and the following ASTM Standards.

- ASTM F2052: 2006 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119: 2007 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182: 11a* Standard Test Method of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213: 2006 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

Zimmer Spine considers the subject *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* to be substantially equivalent to the currently marketed (predicate) *Zimmer Spine Interbody Fusion and Vertebral Body Replacement Device Systems* listed as above because:

- No changes to the intended use,
- No changes to mechanical and functional performance,
- No changes to the functional scientific technology,
- No changes to the implants (screws or rods),
- No changes to the instrumentation,
- No changes to the technological characteristics mentioned above
- No changes to the surgical technique steps